(10) Investigational new animal drug notices, in § 514.12 of this chapter.

(11) New animal drug application files, in § 514.11 of this chapter.

(12) Investigational new animal drug notice and a new animal drug application file for an antibiotic drug, in § 514.10 of this chapter.

(13) Methadone patient records, in § 291.505(g) of this chapter.

(14) Investigational new drug notice, in § 312.130 of this chapter.

(15) Labeling for and lists of approved new drug applications, in § 314.430 of this chapter.

(16) Master file for a new drug application, in § 312.420 of this chapter.

(17) New drug application file, in § 314.430 of this chapter.

(18) Data and information submitted for in vitro diagnostic products, in § 809.4 of this chapter.

(19) Data and information submitted for OTC drug review, in § 330.10(a)(2) of this chapter.

(20) Investigational new drug notice for an antibiotic drug, in § 431.70 of this chapter.

(21) Antibiotic drug file, in § 314.430 of this chapter.

(22) Data and information submitted for biologics review, in § 601.25(b)(2) of this chapter.

(23) Investigational new drug notice for a biological product, in § 601.50 of this chapter.

(24) Applications for biologics licenses for biological products, in § 601.51 of this chapter.

(25) Cosmetic establishment registrations, in § 710.7 of this chapter.

(26) Cosmetic product ingredient and cosmetic raw material composition statements, § 720.8 of this chapter.

(27) Cosmetic product experience reports, in § 730.7 of this chapter.

(28) Device premarket notification submissions, in § 807.95 of this chapter.

(29) Electronic product information, in §§ 1002.4 and 1002.42 of this chapter.

(30) Data and information submitted to the Commissioner or to classification panels in connection with the classification or reclassification of devices intended for human use, in § 860.5 of this chapter.

(31) Data and information submitted in offers to develop a proposed performance standard for medical devices, in § 861.26 of this chapter.

(32) Investigational device exemptions in § 812.38 of this chapter.

(33) Health claims petitions, in § 101.70 of this chapter.

(34) Premarket approval application, in § 814.9 of this chapter.

(35) Report of certain adverse experiences with a medical device, in § 803.9 of this chapter.

(36) Disqualification determination of an institutional review board, in § 56.122 of this chapter.

(37) Disqualification determination of a nonclinical laboratory, in § 58.213 of this chapter.

(38) Minutes or records regarding a public advisory committee, in § 14.65(c) of this chapter.

(39) Data submitted regarding persons receiving an implanted pacemaker device or lead, in § 805.25 of this chapter.

(40) Humanitarian device exemption application, in § 814.122 of this chapter.

[42 FR 15616, Mar. 22, 1977, as amended at 42 FR 19989, Apr. 15, 1977; 42 FR 42526, Aug. 28, 1977; 42 FR 58889, Nov. 11, 1977; 43 FR 32993, July 28, 1978; 51 FR 22475, June 19, 1986; 54 FR 9038, Mar. 3, 1989; 58 FR 2533, Jan. 6, 1993; 59 FR 536, Jan. 5, 1994; 61 FR 33244, June 26, 1996; 62 FR 40592, July 29, 1997; 64 FR 56448, Oct. 20, 1999; 67 FR 13717, Mar. 26, 2002]

### § 20.101 Administrative enforcement records.

(a) All Food and Drug Administration records relating to administrative enforcement action disclosed to any member of the public, including the person who is the subject of such action, are available for public disclosure at the time such disclosure is first made. Such records include correspondence with companies following factory inspection, recall or detention requests, notice of refusal of admission of an imported product, regulatory letters, information letters, Forms FD–483 and FD–2275 furnished to companies after factory inspection, and similar records.

(b) To the extent that any of such records fall within the exemption for investigatory records established in § 20.64, the Commissioner determines that they are subject to discretionary release pursuant to § 20.82.

(c) Records relating to administrative enforcement action that are not disclosed to any member of the public constitute investigatory records that are subject to the rules for disclosure established in § 20.64. For example, an establishment inspection report is an investigatory record and thus subject to § 20.64 except insofar as the Commissioner exercises his discretion to release it pursuant to § 20.82.

### § 20.102 Court enforcement records.

(a) All records and documents filed in the courts are available for public disclosure unless the court orders otherwise. The Food and Drug Administration will make available for public disclosure such records or documents if the agency can determine that it has an accurate copy of the actual record or document filed in the court. If the Food and Drug Administration cannot determine whether it has an accurate copy of such a record or document, the person requesting a copy shall be referred to the court involved.

(b) After a recommendation for court action has been finally refused by a United States attorney, the correspondence with the United States attorney and the Department of Justice with respect to that recommendation, including the pleadings recommended for filing with the court, is available for public disclosure. Prior to disclosure of any record specifically reflecting consideration of possible criminal prosecution of any individual, all names and other information that would identify an individual who was considered for criminal prosecution but who was not prosecuted shall be deleted unless the Commissioner concludes that there is a compelling public interest in the disclosure of such names.

### § 20.103 Correspondence.

(a) All correspondence to and from members of the public, members of Congress, organization or company officials, or other persons, except members of the Executive Branch of the Federal Government and special government employees, is available for public disclosure.

(b) Any such correspondence is available for public disclosure at the time that it is sent or received by the Food and Drug Administration unless a different time for such disclosure is specified in other rules established or cross-referenced in this part, e.g., correspondence relating to an IND notice or an NDA in § 314.430 of this chapter.

[42 FR 15616, Mar. 22, 1977, as amended at 54 FR 9038, Mar. 3, 1989]

### § 20.104 Summaries of oral discussions.

(a) All written summaries of oral discussions, whether in person or by telephone, with members of the public, members of Congress, organization or company officials, or other persons, except members of the Executive Branch of the Federal government or special government employees, are available for public disclosure.

(b) Any such summary is available for public disclosure at the time that it is prepared by the Food and Drug Administration unless a different time for such disclosure is specified in other rules established or cross-referenced in this part, e.g., summaries of oral discussions relating to a food additive petition in § 171.1(h)(3) of this chapter.

(c) If more than one summary of an oral discussion exists in a Food and Drug Administration file, all such summaries shall be disclosed in response to any request for such summary.

### § 20.105 Testing and research conducted by or with funds provided by the Food and Drug Administration.

(a) Any list that may be prepared by the Food and Drug Administration of testing and research being conducted by or with funds provided by the Food and Drug Administration is available for public disclosure.

(b) Any contract relating to agency testing and research, and any progress report relating thereto, is available for public disclosure.

(c) The results of all testing or research conducted by or with funds provided by the Food and Drug Administration, such as toxicological testing, compliance assays, methodology studies, and product testing, are available for public disclosure when the final report is complete and accepted by the